REMARKS

STATUS OF CLAIMS

Prior to entry of this amendment, claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111 and 113-156 were pending and claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-105 and 129-133 were withdrawn from consideration. Examination of the previously withdrawn claims is noted with appreciation.

Page 2 of the Office Action dated November 28, 2006 states that pursuant to the response filed September 9, 2005, claims 22, 64 and 106 have been amended. Although claims 22, 64 and 106 were amended, claims 32, 36, 38, 45, 51, 52, 68, 80-82, 99, 100, 108, 111, 115-118 and 128 were also amended in the response filed September 9, 2005.

By virtue of this response, claims 38, 126, 127 and 145 have been cancelled; claims 22, 32, 36, 51, 53, 54, 64, 75, 79, 106, 111, 114, 119, 124, 125, 143, 146 and 155 have been amended; and new claims 157-168 have been added. The Examiner has withdrawn claim 129 from consideration. Accordingly, after entry of this amendment, claims 22, 23, 26, 32, 35, 36, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-125, 128, 130-144, and 146-168 will be under consideration.

With respect to all amendments and cancellations, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional application. No new matter has been added by the new or amended claims.

CLAIM AMENDMENTS

Claims 22 has been amended as explained in detail below. Support for the $-CH_2OCH_2-$ amendment to claim 22 may be found, e.g., at page 4, lines 30-34 of the specification, and at page 20, lines 6-9 as well as the numerous examples of conjugates throughout the specification. Support

for the amendment regarding valency may be found, e.g., in formulae 1 and 2 starting on page 4 and the numerical designations on page 6, lines 28-34 as well as the numerous examples of conjugates throughout the specification. Support for the requirement of a linker group may be found, e.g., on page 9, line 28 to page 10, line 10 and throughout the specification wherein linker groups link the biologically active molecules to the valency platform molecule.

Claims 32, 75 and 143 have been amended to recite certain biologically active molecules. Support for this amendment may be found, e.g., on page 3, line 35 to page 4, line 9, on page 18, lines 16-18 and pages 20-22.

Claims 36, 51, 53, 79 and 146 have been amended to recite "in an individual" in accordance with the specification's teaching of use of the compositions in an individual. Claim 53 has also been amended to depend from claims 22 or 52.

Claim 54 has been amended to recite particular linking groups and is supported, e.g., by page 9, lines 27-31 and by Example 3.

Claim 64 has been amended. Support for the amendments similar to those of claim 22 are listed above for claim 22. Claim 64 has also been amended to recite particular branching in connection with certain conjugates. Support for this amendment may be found, e.g., on page 19, lines 17-19 and on page 20, lines 4-9.

Claim 106 has been amended to recite the functional group discussed above under claim 22 and to provide antecedent basis for the term "biologically active molecules" for certain dependent claims.

Claims 111, 114, 119, 124, 125 and 155 have been amended to modify dependencies.

Support for new claims reciting polynucleotides wherein the polynucleotide is DNA may be found, e.g. on page 4, line 7, on page 19, lines 29-32 and on page 20, lines 16-30. Support for new claims relating to valency may be found as listed in claim 22 above. Support for new claims relating to alternating nucleotides may be found, e.g., on page 23 and in the examples. Support for new claims relating to polynucleotide length may be found, e.g., on page 20, starting at line 15.

CLAIM REJECTIONS

Obviousness-Type Double Patenting

Claims 22 and 64 over claim 1 of U.S. Patent No. 5,276,013

Claims 22 and 64 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claim 1 of U.S. Patent No. 5,276,013 ("the '013 patent"). Applicants respectfully disagree and seek withdrawal of the obviousness-type double patenting rejection of claims 22 and 64 over claim 1 of the '013 patent.

A reference, *Double Patenting Recapitulated*, 87 J. Pat & Trademark Off. Soc'y 625 (2005), authored by two Morrison & Foerster LLP attorneys, is included with this response in Appendix A. This reference explains how an obviousness-type double patenting test is applied.

The proper comparison in an obviousness-type double patenting analysis is the subject matter defined by the conflicting claims. Professor Chisum explains in Chapter 9, § 9.03 of *Chisum on Patents*: "Double patenting is concerned with attempts to claim the same or related subject matter twice. Thus, the standard for comparison for the second patent is what was claimed in the first patent, not what was disclosed in the specification of the first patent.". Although a patent's specification may be used to help determine the meaning of claims, the claims must be read as a whole and reviewed for the subject matter they define. *Id.*

A two-part inquiry is used to determine whether claims in the commonly owned patent render the claims in the pending patent application obvious. *Double Patenting Recapitulated*, 87 J. Pat & Trademark Off. Soc'y 625, 629 (2005). First, the conflicting claims are construed and their differences determined. *Id.* Second, a determination is made as to whether the differences between the claims render the subject matter defined by the claims of the patent application patentably distinct from the subject matter defined by the claims of the commonly owned patent. *Id.*

In reviewing pending claim 22 or 64 in view of claim 1 of the '013 patent, the conflicting claims should be construed, compared and their differences determined. Specifically, claim 1 should be reviewed as a whole for the subject matter it defines. Claim 22 or 64 should be similarly reviewed. The differences between claim 1 of the '013 patent and claim 22 or 64 of the present application should then be identified and examined for whether they render claim 22 or 64 patentably distinct from claim 1 of the '013 patent. That is, do the host of conjugates defined by claim 1 of the '013 patent as a whole render the chemically defined conjugates defined by claim 22 or 64 obvious to a person of skill in the art?

The subject matter defined by claim 1 of the '013 patent does not suggest a conjugate where the valency platform molecule of the conjugate has specific structural and chemical features, such as those claimed in claim 22 or 64. The '013 patent specification discloses a variety of diverse substances that qualify as valency platform molecules in accordance with the claimed conjugates. For instance, column 4, lines 38-55 of the '013 patent state that a valency platform molecule is typically a polymer, such as PEG, poly-D-lysine, polyvinyl alcohol, polyvinylpyrollidone, immunoglobulins and D-EK. Another substance that may be a valency platform molecule is depicted at the top of columns 17 and 18 of the '013 patent. Thus, the subject matter defined by claim 1 of the '013 patent includes conjugates where the valency platform molecule of the conjugate may be a set of substances of diverse chemical structure, from polymers such as polyvinyl alcohol, PEG and D-EK to immunoglobulins. Claim 1 of the '013 patent does not suggest conjugates of any particular valency platform molecule and does not suggest conjugates where the valency platform molecule of the conjugates has the presently claimed features, such as particular chemical moieties, branching groups, and a defined valency. Rather, claim 1 of the '013 patent describes a set of

conjugates without regard to the chemical and structural features of the valency platform molecule of the conjugate. The chemical and structural features of the conjugates presently claimed would not have been obvious from a claim reciting conjugates without regard to such features. Accordingly, claims 22 and 64 are not obvious over claim 1 of the '013 patent and Applicants respectfully request withdrawal of the present rejection.

The Examiner appears to argue that *In re Kaplan*, a Federal Circuit decision discussed in Applicants' previous responses, is factually distinguishable from the present case because the claims under examination in *Kaplan* were Jepson claims that the Examiner believes are not subgeneric to the earlier issued claims. First, claim format is not relevant to an obviousness-double patenting analysis. This was not a factor even discussed by the Federal Circuit decision in *Kaplan*. Second, the Federal Circuit stated that the pending claims at issue in *Kaplan*, "look very much like a quite specific species of the genus "organic solvent." *In re Kaplan*, 789 F.2d at 1577. A genus claim in a commonly owned patent and a species claim in a later pending application is, according to the Federal Circuit in *Kaplan,* a "commonplace situation [and] is not, per se, doubling patenting . . ." *Id* at 1577-78. The fact that both genus and species claims may be infringed by certain third party conduct provides no insight into whether the differences between the earlier genus claims and the later species claims are obvious. Although a species claim will generally render a genus claim obvious, a genus claim, without more, will generally not render obvious the narrower subject matter of the species claim. *Double Patenting Recapitulated*, 87 J. Pat & Trademark Off. Soc'y 625, 630-632 (2005).

In making the present rejection, the Examiner notes that the disclosure of the '013 patent is not being used as prior art but is used to determine what is encompassed by claim 1 of the '013 patent. The Examiner has every right to confer the patent disclosure of the '013 patent; Applicants have not and are not suggesting that *In re Kaplan* confers "immunity" from obviousness double patenting rejections. Rather, Applicants argue that the proper standard of review has not been applied in the present rejection because an obviousness-type double patenting analysis involves reviewing claims as a whole for the subject matter they define in their entirety, not for particular embodiments that happen to fall within the scope of, but are not suggested by, the claim in question.

Claim 1 of the '013 patent defines a broad range of conjugates and provides no suggestion for conjugates of a particular valency platform molecule. As in *Kaplan,* where an obviousness-type double patenting rejection was improperly imposed on a species claim in view of a genus claim where there was adequate support in the genus specification for the term "organic solvent" apart from the particular mixed solvent disclosed in the genus patent but claimed in the species application, Applicants here have adequate support for the term "valency platform molecule" in claim 1 of the '013 patent apart from the particular valency platform molecule depicted at the top of claims 17 and 18 of the '013 patent specification. As such, the subject matter defined by the entirety of claim 1 includes conjugates of valency platform molecules having a host of chemical composition and structure, which fails to suggest the specific conjugates defined by present claim 22 or 64, which require the valency platform molecule of the conjugate to have specific chemical and structural features.

Lastly, the Examiner states that, under *In re Baird,* it is appropriate for the Examiner to consider species and subgenera that are disclosed in the description of the issued patent in making an obviousness-type double patenting rejection. *In re Baird* concerned an obviousness rejection under 35 U.S.C. § 103 and not the judicially created doctrine of obviousness-type double patenting, which involves different considerations from a 35 U.S.C. § 103 rejection. The proper object of comparison in an obviousness-type double patenting analysis are the claims of the earlier patent and the claims of the later application and whether the differences in subject matter between the two claims is obvious. The Examiner has not considered species and subgenera of the claims in rendering the present rejection. As noted above, the claims of the earlier patent must be reviewed in their entirety, not for particular embodiments that are within the scope of, but not suggested by, the claim in question.

For the reasons presented above, the subject matter of claim 22 or 64 is not rendered obvious by the subject matter of claim 1 of the '013 and Applicants respectfully request withdrawal of the present rejection.

Claims 22 and 64 over claim 1 of U.S. Patent No. 6,060,056

Claims 22 and 64 are rejected over claim 1 of U.S. Patent No. 6,060,056 ("the '056 patent"). Applicants traverse this rejection for the same reasons presented above with regard to a similar rejection over the '013 patent. Namely, under the proper analysis, the structural features of the presently claimed conjugates would not have been obvious from claim 1 of the '056 patent, which does not suggest conjugates where the valency platform molecule of the conjugates has the presently claimed features, such as particular chemical moieties, branching groups, and a defined valency. Rather, claim 1 of the '056 patent describes a set of conjugates without regard to the chemical and structural features of the valency platform molecule of the conjugate. The chemical and structural features of the conjugates presently claimed would not have been obvious from a claim reciting conjugates without regard to such features. Accordingly, Applicants respectfully request withdrawal of the obviousness-type double patenting rejection of claims 22 and 64 over claim 1 of the '056 patent.

Claims 22 and 64 over claim 9 of U.S. Patent No. 5,552,391

A terminal disclaimer over U.S. Patent No. 5,552,391 in enclosed together with this response, rendering the present rejection moot.

Claims 22 and 64 over claims 22 and 32 of U.S. Application No. 09/753,350

Applicants note the provisional nature of the present rejection and will address the merits upon receiving an indication of otherwise allowable subject matter.

Claims 22, 64, 78 and 80 over claim 46 of U.S. Application No. 09/590,592 and claim 68 over claim 54 of U.S. Application No. 09/590,592

Applicants note the provisional nature of the present rejection and will address the merits upon receiving an indication of otherwise allowable subject matter. However, Applicants note for the Examiner that U.S. Patent Application 09/590,592 was abandoned in favor of U.S. Patent Application Nos. 10/867,874 and 11/303,591.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-128 and 130-156 are rejected as allegedly failing to comply with the written description requirement. The Examiner contends that descriptive support is lacking for the recitation of the functional group $-O-CH_2-CH_2-O-$ and for the requirement that the valency of the platform molecule is provided by four or more attachment sites located at termini of the valency platform molecule. Applicants respectfully disagree and address each of the Examiner's concerns in turn below.

The present claims are rejected for the recitation of valency platform molecules comprising the functional group $-O-CH_2-CH_2-O-$ on the basis that "nowhere in the specification is there any suggestion that the VPM can comprise the functional group in question." Applicants respectfully disagree. The specification contains descriptive support for valency platform molecules comprising a polyethylene glycol ("PEG") moiety. A valency platform molecule containing a PEG moiety necessarily comprises the functional group $-O-CH_2-CH_2-O-$. The specification also contains support for a valency platform molecule having a monomer of ethyleneoxide. For instance, page 4, lines 30-34 of the specification provide that a valency platform molecule may comprise the moiety $-CH_2(CH_2OCH_2)_rCH_2-$ where r = 0-300; when r is 2, the valency platform molecule contains the monomeric functional group $-O-CH_2-CH_2-O-$. The specification at page 20, line 6 also states that examples of particularly preferred valency platform molecules include derivatized 2,2'-ethylenedioxyditheylamine (i.e., derivatized $NH_2CH_2CH_2OCH_2CH_2OCH_2CH_2NH_2$), which contains the monomeric functional group $-O-CH_2-CH_2-O-$. As to conjugates of valency platform molecules comprising triethyleneglycol moiety, page 20, lines 6-9 of the specification as filed, states that examples of particularly preferred valency platform molecules include derivatized 2,2'-ethylenedioxyditheylamine, *triethylene glycol* and polyethylene glycols having a molecular weight of about 200 to about 8,000. A person of skill in the art would understand from the specification, such as from the examples listed above, that the inventors conceived of conjugates of valency platform molecules having a monomeric functional group $-O-CH_2-CH_2-O-$ or a polymer thereof.

However, in order to expedite prosecution, Applicants have amended independent claims 22, 64 and 106 to recite the functional group $-CH_2OCH_2-$ in place of the functional group $-O-CH_2-CH_2-O-$ so as to conform the claims to the notation of the functional group in the formula – $CH_2(CH_2OCH_2)_rCH_2-$. The specification provides descriptive support for this amendment and each of the moieties claimed in section (a) of claims 22, 64 and 106 contain the newly presented functional group.

Applicants respectfully contend that the specification as filed also provides written description support for the claim limitation requiring the valency of the platform molecule to be provided by four or more attachment sites located at termini of the valency platform molecule.

Formulae 1 and 2 listed on page 4 of the specification as filed depict valency platform molecules. In these formulae, the moiety T represents a terminus of the valency platform molecule and is the moiety, or attachment site, rendering the valency platform molecule amenable to conjugation with a biologically active molecule. Further, as shown in formulae 1 and 2, the number of T moieties is dictated by the variable n, which can be a value up to 32, including the value 4: "$n^{[1]}$ = 1 to 32 . . . most preferably $n^{[1]}$ = 2 to 4"; "$n^{[2]}$ = 1 to 32 . . . yet more preferably $n^{[2]}$ = 1 to 4.").

Ipsis verbis recitation of claim terms in the specification is not required for compliance with the written description requirement of 35 U.S.C. §112. MPEP § 2163(II)(A). A specification which provides description of the claimed invention such that a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, will have satisfied the written description requirement, "even if every nuance of the claims is not explicitly described in the specification." *Id.* Although the moieties listed as T in formulae 1 and 2 do not explicitly recite the terms "terminus" or "termini", it is clear to a person of skill in the art that the moieties are located at the termini of the valency platform molecule and are attachment sites for biologically active molecules. Further, the formulae indicate that the valency of the platform molecules may be provided by four or more attachment sites. Accordingly, there is support in the specification as filed for conjugates of a biologically active molecule and a valency platform molecule where the valency

of the platform molecule is provided by four or more attachment sites located at termini of the valency platform molecule.

Applicants note that independent claims 22, 64 and 106 have been amended to recite conjugates wherein the valency of the platform molecule of the conjugate is provided by at least four but no more than 32 attachment sites located at termini of the valency platform molecule. This amendment is expressly supported by the specification as stated above.

The claims as a whole are fully supported by the specification as filed. Applicants reiterate from their September 9, 2005 response that the specification supports the combined features as claimed. For instance, page 20, lines 3-9 recite valency platform molecules as "derivatized" moieties and page 19, lines 14-17 recite that branching groups are "added to" the platform molecules. The specification provides descriptive support for the claimed invention, including a valency platform molecule comprising an ethyleneoxide moiety (page 20, lines 6-9); branching groups (page 19, lines 19); and valency as a function of branching groups (which in turn give rise to attachment sites) (page 19, lines 14-17). Applicants respectfully request withdrawal of the 35 U.S.C. §112, first paragraph rejection of claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-111, 113-128 and 130-156.

Enablement

Claims 38, 127 and 145 are rejected as allegedly failing the enablement requirement of 35 U.S.C. § 112. Applicants have cancelled claims 38, 127 and 145 to reduce the number of issues presented for current prosecution, thereby rendering the Examiner's rejection of these claims moot. Applicants have not acquiesced to the present rejection and reserve the right to pursue the subject matter of claims 38, 127 and 145.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 22, 23, 26, 32, 35, 36, 38, 43, 45, 46, 51-54, 64-77, 79-82, 84, 86, 89, 99-11, 113-128 and 130-156 are rejected as allegedly indefinite. The particular rejections are addressed below in the same order as presented in the Office Action.

Claim 22 is rejected for recitation of the functional group $-O-CH_2-CH_2-O-$ and the designation r = 0 to 300. Applicants do not believe that the claim is indefinite because one of skill in the art would understand from the entirety of claim 22 that "r" must be greater than zero. However, in order to expedite prosecution of the present application, Applicants have amended the claims to recite r where r = 1 to 300. This amendment reflects the claim format in, e.g., dependent claims 81 and 82, which were previously presented and recited the instant limitation. Applicants respectfully request withdrawal of present rejection in view of the arguments and/or amendment.

Claims 36, 51, 53 and 146 have been rejected for recitation of the phrase "suitable for reducing antibody levels." These claims have been amended to recite "suitable for reducing antibody levels in an individual." Applicants respectfully request withdrawal of the rejection in view of this amendment.

Claims 135, 149 and 150 have been rejected for lacking antecedent basis for the term "biologically active molecules." However, claim 135 refers to claim 22, 64 or 106, each of which recites the phrase biologically active molecules. Applicants note that claim 106 has been amended in this response to explicitly recite the phrase biologically active molecules. Similarly, claims 149 and 150 are dependent claims that ultimately refer to claim 64, which recites the phrase biologically active molecules. Accordingly, there is antecedent basis for "biologically active molecules" for each of claims 135, 149 and 150 and Applicants seek withdrawal of the present rejection.

Claim 79 has been rejected for recitation of the phrase "suitable for injection." One of skill in the art would understand claim 79 in light of the specification, such as page 29 which indicates that the conjugates will normally be formulated for administration by injection "e.g., intraperitoneally, intramuscularly, intravenously." However, in order to expedite prosecution, claim

79 has been amended to recite injection in an individual. Applicants seek withdrawal of the present rejection in view of the comments above and/or amendment to claim 79.

Rejections under 35 U.S.C. § 103

Claims 22 and 54 are rejected under 35 U.S.C. § 103 as allegedly obvious over U.S. Patent No. 5,648,506 ("the '506 patent") to Desai.

The Examiner has rejected claims 22 and 54 as allegedly obvious over the '506 patent on the basis that "Desai discloses branched molecules containing PEG and taxol." This statement does not establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, there basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference, (2) there must be a reasonable expectation of success, and (3) the prior art reference must teach or suggest all of the claim limitations. MPEP §§ 706.02(j) and 2142. The Examiner has the initial burden to explain why the reference suggests what is now claimed or present a convincing line of reasoning as to why a person of skill in the art would find obvious what is presently claimed. *Id.* The Examiner has not met the initial burden because there is no explanation or line of reasoning presented to establish any of the three basic criteria needed to establish a *prima facie* case of obviousness. However, the merits of the rejection are addressed below.

The '506 patent discloses polymeric carriers to assist in the drug delivery of taxol, and discloses branched molecules containing PEG and taxol. As stated in column 6, lines 36-40, "the number of available sites for coupling the drug to the 'brush-like' polymer was dependent on the number of PEGs having a free hydroxyl group that were incorporated into the growing polymer chain during the polymerization process." However, the branched polymeric carriers of the '506 patent fail to suggest each of the features claimed in claim 22 or 54. Namely, claims 22 and 54 require that the moieties stated in part (a) of claim 22 are derivatized with branching groups and that the valency is provided by attachment sites located at termini of the valency platform molecule. The conjugates of claims 22 and 54 have distinct components: the moieties in part (a) which are derivatized with the branching groups and the attachment sites located at termini of the valency

platform molecule. The '506 patent does not suggest conjugates of branched valency platform molecules in the same sense as in the presently rejected claims because there is no suggestion for –OCH_2CH_2O- containing moieties derivatized with branching groups as required by the previously pending claims. Similarly, the '506 patent does not suggest -CH_2OCH_2- containing moieties derivatized with branching groups as required in the currently amended claims. Further, claims 22 and 54 require that attachment sites be located at termini of the valency platform molecule. In the '506 patent, the repeating PEG units and –OH groups used to conjugate the polymer to taxol are located throughout the body of the polymer platform and not limited to the termini of the polymers nor is there a suggestion that they should be so limited. Because there is no suggestion in the '506 patent for conjugates of valency platform molecules comprising PEG moieties derivatized with branching groups or where attachment sites of the valency platform molecule are located at termini of the platform, the '506 does not render claim 22 or claim 54 obvious.

Claims 22 and 54 are rejected under 35 U.S.C. § 103 as allegedly obvious over U.S. Patent No. 5,171,264 ("the '264 patent) to Merrill.

The Examiner has rejected claims 22 and 54 as allegedly obvious over the '264 patent on the basis that Merrill discloses branched molecules containing polyethylene glycol, which can be viewed as a conjugate of $(OCH_2CH_2)_{n-1}$ and ethanol. These statements do not establish a *prima facie* case of obviousness. In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference, (2) there must be a reasonable expectation of success, and (3) the prior art reference must teach or suggest all of the claim limitations. MPEP §§ 706.02(j) and 2142. The Examiner has the initial burden to explain why the reference suggests what is now claimed or present a convincing line of reasoning as to why a person of skill in the art would find obvious what is presently claimed. *Id.* The Examiner has not met the initial burden because there is no explanation or line of reasoning presented to establish any of the three basic criteria to establish a *prima facie* case of obviousness. However, the merits of the rejection are addressed below.

The '264 patent discloses immobilizing polyethyleneoxide star molecules in the form of hydrogels. The '264 patent discloses polymeric platforms containing an 'arm' of polyethyleneoxide to which molecules may be connected. However, the '264 patent fails to suggest each of the features in present claim 22 or 54. Namely, claims 22 and 54 require that the moieties stated in part (a) of claim 22 are derivatized with branching groups and that the valency is provided by attachment sites located at termini of the valency platform molecule. The conjugates of claims 22 and 54 have distinct components: the moieties in part (a) which are derivatized with the branching groups and the attachment sites located at termini of the valency platform molecule. The '264 patent does not suggest conjugates of branched valency platform molecules in the same sense as in the presently rejected claims because there is no suggestion for $-OCH_2CH_2O-$ containing moieties derivatized with branching groups as required by the previously pending claims. Similarly, the '264 patent does not suggest $-CH_2OCH_2-$ containing moieties derivatized with branching groups as required in the currently amended claims. Rather, the PEG moieties in the '264 patent are in the 'arms' to which biologically active molecules are directly connected. Because there is no suggestion in the '506 patent for conjugates comprising PEG moieties derivatized with branching groups, the '264 patent does not render claim 22 or claim 54 obvious.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **252312005704**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 30, 2006

Respectfully submitted,

By _____

Shannon Reaney
Registration No.: 52,285
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304-1018
(650) 813-5744

APPENDIX A

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Double Patenting Recapitulated

Emily A. Evans and Jill A. Jacobson

I. What is Double Patenting?

Under U.S. patent law, the doctrine of double patenting precludes a patentee from holding more than one patent with claims to the same invention or obvious modifications or variations of the same invention.[1] This proscription is grounded in public policy considerations against allowing a patent holder to extend the monopoly afforded by patent protection by obtaining successive patents for the same claimed invention.[2] Requiring claims to a single invention to expire on the same date permits the public to rely on a date certain when the claimed invention will become available for public use.

A. Statutory Basis For Double Patenting

The basis for the double patenting doctrine is provided in the patent statute, which states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain *a* patent therefor..."[3] The word "a" has been interpreted to mean that a patentee may have only one patent covering a particular claimed invention. Therefore, two patents with claims directed to the same invention are not permitted.

B. Judicially-Created Obviousness-Type Double Patenting

The courts have extended the prohibition against multiple patents for identical inventions to include obvious variations of the same invention. Under the judicially-created doctrine of obviousness-type double patenting, a patentee may not have a later-issued patent with claims directed to an obvious variation of the subject matter of claims in an earlier-issued patent. The Federal Circuit has stated that it is fundamental

1 *See, e.g., In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985); *see generally* Chisum on Patents § 9.01.
2 *Id.*
3 35 U.S.C. § 101 (emphasis added).

to the doctrine of double patenting that "[t]he public should...be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill of the art and prior art other than the invention claimed in the issued patent."[4] Obviousness-type double patenting may be cured by filing a terminal disclaimer that ties the term of the later-issued patent to the term of the earlier-issued patent, so that the two patents expire simultaneously, and requires that the two patents remain under common ownership. In contrast, statutorily-based same invention type double patenting cannot be abrogated by filing a terminal disclaimer.

C. Effect Of Double Patenting Doctrine

The double patenting doctrine was developed during an era when the term of a patent was dependent on its issue date, and permitting an applicant to obtain a series of patents with claims directed to the same subject matter would result in timewise extension of the expiration date of the monopoly for a single invention.

Under current law, U.S. patents issuing from applications filed on or after June 8, 1995 have a term expiring twenty years from the earliest claimed priority date. Therefore, successively issuing patents all claiming priority back to the same application now have the same expiration date.[5] Thus, unless a patent term extension is granted, the date on which a patent monopoly will end will not be extended by permitting a series of patents directed to the same invention to issue. However, even for patents with the same expiration date, a terminal disclaimer also has the effect of requiring common ownership of patents subject to the disclaimer. This has been said to provide a benefit to the public by preventing an alleged infringer from being subjected to multiple lawsuits from different parties with regard to the same patented invention.[6]

D. Situations In Which Double Patenting Issues Arise

A double patenting issue may arise in the form of a rejection by the United States Patent and Trademark Office (USPTO) during prosecution

4 *Longi*, 759 F.2d at 892.

5 The terms of these patents may differ, however, because of possible patent term extensions. *See* 35 U.S.C. §§ 154156.

6 *In re Van Ornum*, 686 F.2d 937 (C.C.P.A. 1982).

of a patent application with a co-owned issued or pending counterpart, when a patent examiner believes that the counterpart contains claims to the same invention or an obvious variant thereof.

A double patenting issue may also arise in a patent reexamination context as a "substantial new question of patentability."[7] In *In re Lonardo*,[8] the Federal Circuit held that a co-owned patent entitled to the same filing date as a patent undergoing reexamination, and therefore not qualifying as "prior art," could properly be considered with respect to patent validity on the basis of a double patenting issue. The court stated that because 35 U.S.C. § 303(a) permits the Commissioner "to consider a substantial new question of patentability over 'patents and publications discovered by him'" and "authorizes the Commissioner to consider 'other patents or printed publications' in addition to the prior art submitted by a third party," reexamination is not limited to prior art.[9] Therefore, if the issue of double patenting was not considered during prosecution of a patent application, it may be considered during reexamination.

When a double patenting issue arises in litigation, a defendant asserting invalidity of a patent by virtue of double patenting must present "clear and convincing evidence" to prevail on this issue.[10] Double patenting is a question of law which is reviewed *de novo* by an appellate court.[11] The Federal Circuit has stated that *de novo* review "is appropriate because double patenting is a matter of what is claimed, and therefore is treated like claim construction upon appellate review."[12] If double patenting — either statutory or obviousness-type — is proven, the affected claim is invalid.[13] Invalidity of a claim for double patenting does not affect the validity of any other claim in the patent.[14] This is in contrast to a terminal disclaimer entered during prosecution, which applies to all claims, whether affected by the double patenting issue or not.[15]

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7 *In re Lonardo*, 119 F.3d 960, 966 (Fed. Cir. 1997).

8 *Lonardo*, 119 F.3d 960.

9 *Id.* at 966.

10 *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991); *see also Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990) (finding alleged infringer did not carry its burden on obviousness-type double patenting where it "offered no evidence of the scope and content of the pertinent art, other than [the reference] patent, the level of skill in the art, or what would have been obvious to a person skilled in the art").

11 *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999).

12 *Id.*

13 *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 942 (Fed. Cir. 1992); 35 U.S.C. § 101.

14 *Ortho*, 959 F.2d at 942 (holding that a double patenting challenge during litigation "must be evaluated, like any other ground of validity, against individual claims").

15 *Id.*

In any context, when double patenting is considered each claim must be read as a whole and considered separately in its entirety, and the claims of the two applications/patents are compared to determine whether anything has been claimed twice.[16]

II. Requirements for a Valid Double Patenting Rejection

A double patenting analysis entails a determination as to whether the same invention is being claimed twice in a co-owned application and patent. If so, 35 U.S.C. § 101, which states that an inventor may obtain "a patent, prevents two patents from issuing on the same invention.[17] If the same invention is not being claimed twice, a second analysis must be performed to determine whether any claim in the application is "an obvious variation of an invention disclosed and claimed in the [earlier-issued] patent."[18]

A. Statutory Double Patenting

A statutory double patenting rejection of the "same invention" type requires that a co-owned patent and patent application contain claims directed to identical subject matter. In *In re Vogel*, the Court of Customs and Patent Appeals set forth the test for statutory double patenting.[19] The question is whether the same invention is being claimed in a patent and an application for patent. "Invention" means what is defined in the claims and "same invention" means identical subject matter.[20] The subject matter of the claims must be identical in scope. The *Vogel* court gave the example of a claim reciting "thirty-six inches" and a claim reciting "three feet," which would be of the same scope and would present a statutory double patenting issue if all other limitations of the claims are identical.[21]

The specification may be reviewed if necessary to construe the claims.[22] If one of the claims can be literally infringed without infringing the other claim, *i.e.*, the claims do not "cross-read," the claimed inventions are not identical and should not be subject to a statutory double patenting rejection.[23] In the context of a design and a

16 *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992); *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970).
17 *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970).
18 *Id.*
19 *Id.*
20 *Id.*
21 *Id.*
22 *Id.*
23 *Id.*; *Shelcore v. Durhamindustries, Inc.*, 745 F.2d 621, 628 (Fed. Cir. 1984).

utility patent, the claims cross-read if a device embodying the patentable design of a design patent must infringe the claims of a utility patent, and a device embodying the claims of the utility patent must infringe the design of the design patent.[24]

B. Obviousness-Type Double Patenting

A non-statutory double patenting rejection of the judicially-created "obviousness type" applies when a claim of a patent application defines an invention that is an obvious variation of, or anticipated by, an invention claimed in a commonly-owned patent, *i.e.*, the claimed subject matter is not patentably distinct.[25] An obviousness-type double patenting determination involves a two-part inquiry. First, the claims of the earlier patent and the later patent or patent application are construed, and the differences determined.[26] Second, a determination is made as to whether differences between the two claims render the claimed inventions "patentably distinct."[27] Although the disclosure of a patent involved in a double patenting analysis may not be used as prior art, it may be used to interpret the meaning of a claim.[28]

An obviousness-type double patenting inquiry requires an analysis similar to a determination of obviousness under 35 U.S.C. §103, except that the disclosure of the patent that is the basis of the double patenting rejection is not available as "prior art."[29] In *In re Longi*, the Federal Circuit noted that "a double patenting of the obviousness type rejection is 'analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103,' except that the patent principally underlying the double patenting rejection is not considered prior art."[30]

The USPTO Manual of Patent Examining Procedure states that during prosecution, the patent examiner has the burden of showing a *prima facie* case for obviousness-type double patenting, applying the factual inquiries set forth in *Graham v. John Deere*,[31] *i.e.*, determination of the scope and content of a patent claim and the prior art relative to a

24 *Carman Indus., Inc. v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983).

25 *Vogel*, 422 F.2d at 441.

26 *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).

27 *Id.*.

28 *Vogel*, 422 F.2d at 441; *Research Corp. Techs., Inc. v. Gensia Labs.*, 2001 U.S. App. LEXIS 4444, at *23 (Fed. Cir. 2001) (unpublished).

29 Chisum on Patents §9.03[3]; *In re Longi*, 759 F.2d 887, 892 n.4 (Fed. Cir. 1985); MPEP §804 II.B.1.; *In re Kaplan*, 789 F.2d 1574 (Fed. Cir. 1986); *Vogel*, 422 F.2d at 441.

30 *Longi* at 892 n.4 (citing *In re Braithwaite*, 379 F.2d 594, 600 n.4 (C.C.P.A. 1967)).

31 *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

claim in the patent application at issue, determination of the differences between the scope and content of the patent claim and the prior art and the claim in the application at issue, determination of the level of ordinary skill in the pertinent art, and evaluation of objective indicia of nonobviousness.[32] Evidence of unexpected results may overcome a *prima facie* case of obviousness in a double patenting context.[33] Recently, however, the Federal Circuit stated in *dicta* that a double patenting analysis may be distinguished from an obviousness analysis under 35 U.S.C. § 103 because an obviousness analysis requires a "motivation to modify the prior art" and an "inquiry into objective criteria suggesting non-obviousness," whereas double patenting does not require such a motivation or inquiry.[34]

1. Species Claims Render Later-Issued Genus Claims Obvious

A situation in which an application may be found to violate the rule against double patenting is when the application contains claims to a genus and a commonly-owned earlier-issued patent contains claims to a species of the genus.[35] The genus is anticipated by the species, in violation of the rule against obviousness-type double patenting.

For example, in *In re Vogel*,[36] the court considered a double patenting rejection of claims directed to "a method for prolonging the storage life of packaged *meat* products" in view of an issued patent with claims directed to "a method of preparing *pork* products." First, the court inquired whether the claims were to identical inventions and determined that meat and pork are not the same thing since a claim to "meat" could be infringed by a process that does not infringe a claim limited to "pork." Next, the court considered whether the claims to "meat" in the application were an obvious variation of the claims directed to "pork" in the issued patent, taking into consideration the disclosure of the issued patent that supported the claim of the patent in conjunction with a prior art reference that disclosed a feature of the claim of the application that was missing from the patent claims and disclosure. The court concluded that since the term "meat" encompasses "pork," allowance of the application would extend the time frame of the

32 M.P.E.P. § 804.II.B.1; *see also In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999) (stating that the *Graham* factors are to be applied in a double patenting analysis).

33 *Longi*, 759 F.2d at 896.

34 *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003).

35 *Geneva Pharms.*, 349 F.3d at 1384.

36 *Vogel*, 422 F.2d at 438.

monopoly with respect to the pork process, and the claim directed to the "meat" process was not allowable in the absence of a terminal disclaimer.

Similarly, in *Eli Lilly & Co. v. Barr Laboratories*,[37] the Federal Circuit considered whether a claim directed to administration of a compound to "humans" in an earlier-issued patent was invalid by virtue of obviousness-type double patenting over a claim directed to administration of the compound to "animals" in a later-issued patent. The court held that humans are a species of the animal genus, and a claim to "animals" is therefore not patentably distinct from the earlier-issued "human" species claim.[38]

In contrast, claims to different species of the same genus are not necessarily obvious in view of each other. In *Pharmacia & Upjohn Co. v. Ranbaxy Pharms., Inc.*,[39] the Federal Circuit considered patents with claims to chemical compounds that had the same core structure but differed in the chemical substituent at one position within the structure. The court stated that the plaintiff was likely to withstand a double patenting challenge based on these claims and that "merely establishing that two species are members of the same genus does not prove that one is obvious over the other," and further stated that the examiner's failure to require a terminal disclaimer was "consistent with this principle."[40]

2. Genus claims do not render later-issued improvement claims obvious

In *In re Kaplan*,[41] the Federal Circuit held that an earlier-issued dominant patent did not present a double patenting issue with respect to an application having improvement claims. The issued patent included a claim directed to a chemical process "wherein the reaction is effected in the presence of an organic solvent."[42] The application contained a claim directed to a similar process "the improvement which comprises effecting said reaction in a solvent mixture of tetraglyme and sulfolane...."[43] The recited solvent mixture was a species of the genus "organic solvent" in the issued patent. The court held that this did not constitute double patenting because the public would still be free to use the process in the earlier-issued patent when it expires, so long as the

37 *Eli Lilly*, 251 F.3d 955.
38 *Id.* at 971-72.
39 *Pharmacia & Upjohn Co. v. Ranbaxy Pharms., Inc.*, Nos. 03-1536, 02-1566, 2003 U.S. App. LEXIS 26237 (Fed. Cir. 2003) (unpublished).
40 *Id.* at *16.
41 *Kaplan*, 789 F.2d 1574.
42 *Id.* at 1575.
43 *Id.* at 1575

solvent mixture of the later-issued patent is not used.[44] Also, there was evidence of record that the claimed species was not obvious in view of the earlier genus.[45] This result is the opposite of the situation where a species claim issues first, followed by issuance of a genus claim, preventing the public from using the entire genus, including the species of the earlier-issued patent, for the entire term of the later-issued patent.

3. Inherent features do not render later-issued claims patentably distinct

Recitation of a limitation in a claim of a later-issued patent that is an inherent feature of a claim in an earlier-issued patent does not render the later claim patentably distinct, and thus does not allow a patentee to avoid obviousness-type double patenting. In *Eli Lilly & Co. v. Barr Labs., Inc.*,[46] the Federal Circuit considered the claims of two patents both directed to administration of a fluoxetine hydrochloride (the active ingredient in Prozac). The claim of the earlier-issued patent recited administration of the compound in a method of treating anxiety in humans, whereas the claim in the later-issued patent recited administration of the compound in a method to block serotonin uptake in animals. The court held that since serotonin uptake is an inherent biological property of fluoxetine hydrochloride upon its administration, "no patentable distinction rests between administering fluoxetine hydrochloride for treatment of anxiety and inhibition of serotonin uptake by administration of fluoxetine hydrochloride."[47] The other difference between the two claims was that the earlier claims were directed to humans and the later claims were directed to animals. Because humans are a species of animals, the later-issued genus claims were found to be anticipated by — and therefore not patentably distinct from — the earlier species claims.[48]

4. "One-Way" Versus "Two-Way" Test for Determination of Obviousness-Type Double Patenting

A. One-Way Obviousness Analysis

In most cases, a "one-way" test is applied to determine whether obviousness-type double patenting exists. Under the one-way test, if the scope of the claims in the application and the issued patent is not

44 *Id.* at 1578.
45 *Id.* at 1580.
46 *Eli Lilly,* 251 F.3d 955.
47 *Id.* at 971.
48 *Id*

identical, an inquiry is made as to whether the claims of the application are patentably distinct from the claims of the patent.[49] Application claims are patentably distinct when they are neither obvious nor anticipated by the claims of the issued patent.[50]

B. Two-Way Obviousness Analysis

In certain limited circumstances, a "two-way" test is applied. The policy behind a two-way analysis is "to prevent rejections for obviousness-type double patenting when the applicants filed first for a basic invention and later for an improvement, but, through no fault of the applicants, the PTO decided the applications in reverse order of filing, rejecting the basic application although it would have been allowed if the applications had been decided in the order of their filing."[51] A two-way analysis is used when the applicant could not have filed the claims in a single application *and* the later-filed application issues first due to administrative delay on the part of the Patent Office.[52] In a two-way analysis, a double patenting rejection is appropriate only when the claims of the two patents cross-read on each other, viz., when "the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the claims of the other patent, and vice versa."[53]

Filing claims in two separate applications, when the claims could have been filed in a single application, precludes a two-way double patenting analysis. In *In re Berg*,[54] the Federal Circuit considered a fact scenario where an applicant filed two almost-identical applications simultaneously with different claims, and the application with the narrower claims issued first.[55] The court held that simultaneously filing two separate applications that could have been filed as one application disqualified the applicant from the benefit of the two-way test.[56] The court stated that "Berg should be viewed as having taken a calculated risk that, by simultaneously filing two separate applications, it might gain the advantage of a quickly issued, narrow patent and also the advantage of a broader application which took longer to issue as a patent

49 *Eli Lilly and Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001).
50 *Id.*; *see also In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).
51 *Berg*, 140 F.3d at 1432.
52 *Id.* at 1435.
53 *Carman*, 724 F.2d 932 at 940.
54 *Berg*, 140 F.3d 1428.
55 *Id.* at 1430-31.
56 *Id.* at 1435..

but consequently had a later expiration date.[57] Effectively extending the patent term, however, is precisely the result that the doctrine of obviousness-type double patenting was created to prevent."[58]

A delay in issuance of a patent on the part of the applicant also precludes a two-way analysis. In *In re Goodman*,[59] the Federal Circuit held that a two-way obviousness analysis did not apply when a patentee chose to let narrow species claims issue first, followed by filing of a continuation application with claims to the broader genus. The court held that since Patent Office actions did not dictate the rate of prosecution, thereby causing the two applications to issue at different times, the earlier-issued species claims precluded issuance of the genus claims in the absence of a terminal disclaimer.[60] Similarly, the court in *In re Emert* held that a delay on the part of the applicant that entailed obtaining extensions of time and twice filing a continuation application rather than responding to an Office Action precluded a two-way analysis, because the applicant controlled the rate of prosecution rather than the Patent Office.[61]

III. Overcoming a Double Patenting Rejection

When faced with a double patenting rejection during prosecution of a patent application, the applicant may argue that the two sets of claims are directed to patentably distinct inventions or may amend the claims of the pending application to avoid subject matter overlap. For a statutory-based "same invention" double patenting rejection, these are the only avenues available to avoid double patenting. For obviousness-type double patenting, the applicant has the additional available option of filing a terminal disclaimer.

A. Terminal Disclaimer Requirements

The requirements for a terminal disclaimer filed to obviate a judicially-created double patenting rejection are set forth in 37 C.F.R. §1.321(c). Filing a terminal disclaimer ties the term of the later-issued patent to the expiration date of the earlier-issued patent.[62] A terminal disclaimer filed with respect to one patent is not tied to other related patents.[63]

57 *Id.*
58 *Id.*
59 *In re Goodman*, 11F.3d 1046 (Fed. Cir. 1993).
60 *Id.* at 1053.
61 *In re Emert*, 124 F.3d 1458, 1461 (Fed. Cir. 1997).
62 *See* 37 C.F.R. § 1.321(c).
63 *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 941-42 (Fed. Cir. 1992).

Among other requirements, the disclaimer must "include a provision that any patent granted on that application or any patent subject to reexamination proceeding shall be enforceable only for and during such period that said patent is commonly owned with the application or patent which formed the basis for the rejection."[64] The requirement that a patent subject to terminal disclaimer must be commonly owned with the application forming the basis for a double patenting rejection stems from the public policy consideration of preventing multiple suits against an accused infringer on related patents by multiple parties.[65] Thus, filing a terminal disclaimer is equivalent to having all of the claims in one patent, with common ownership throughout the life of the patent.[66]

A terminal disclaimer "simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection."[67] The Federal Circuit has held that challenging a double patenting rejection prior to filing a terminal disclaimer "does not change the effect of such disclaimer and cannot be inferred by a reasonable juror to raise an inference of infringement under the doctrine of equivalents just as it cannot be inferred to raise an inference of invalidity under 35 U.S.C. §103."[68]

IV. Interplay Between Double Patenting and 35 U.S.C. § 121

There is an interplay between obviousness-type double patenting and restriction practice under 35 U.S.C. § 121. Section 121 of Title 35 provides, in pertinent part:

> "If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions.... A patent issuing on an application with respect to which a requirement for restriction ... has been made, or on an *application filed as a result of such a requirement*, shall not be used as a reference either in the [USPTO] or in the courts against a divisional application or against the original application."[69]

64 37 C.F.R. §1.321(c)(3).
65 *Van Ornum*, 686 F.2d at 944.
66 *Id.* at 948.
67 *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874 (Fed. Cir. 1991).
68 *Id.*
69 35 U.S.C. § 121 (emphasis added).

Thus, Section 121 provides a safe haven from obviousness-type double patenting in divisional applications filed as a result of a restriction requirement by the examiner in the parent application.

Further, so long as the divisional application is filed "as a result" of the restriction requirement, "Section 121[3] effects a form of estoppel that shields the applicant from having to prove the correctness of the restriction requirement in order to preserve the validity of the second patent."[70] In other words, Section 121 "assures that the technicalities of restriction practice are not elevated...to a potential taint on the validity of the ensuing patents."[71]

In order to get the protection of Section 121, the restriction requirement "must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121's protections."[72] For example, in a recent case, the Federal Circuit ruled Section 121 was not available where the alleged restriction requirement consisted of a statement in an examiner interview summary record that certain claims would be "proper" in the application while others would not be "proper."[73] This was found to be insufficient to conclude that a restriction requirement under 35 U.S.C. § 121 had been entered and, if so, what that restriction requirement was.[74]

In order to retain the benefit of Section 121, "the claims in a divisional application must be consonant with those not elected under that requirement."[75] As explained by the Federal Circuit:

> Consonance requires that the line of demarcation between the "independent and distinct inventions" that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed by the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.[76]

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70 *Studiengesellschaft Kohle mbH v. Trustee for Max-Planck Inst.*, 784 F.2d 351, 360-61 (Fed. Cir. 1986) (Newman, J., concurring).

71 *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996).

72 *Geneva Pharms.*, 349 F.3d at 1381.

73 *Id.*

74 *Id.* at 1381-82.

75 *Gerber*, 916 F.2d at 685.

76 *Id.* at 688; *accord Geneva Pharm.*, 349 F.3d at 1381.

Thus, "[a] restriction requirement does not prohibit subsequent amendments to the claims," so long as consonance with the restriction requirement is preserved.[77] "However, even if such consonance is lost, double patenting does not follow if the requirements of § 121 are met or if the claims are in fact patentably distinct."[78]

Applicants have the responsibility to insure that the claims in the divisional application remain consonant with the parent. Adding a claim in the divisional application that is not consonant with the restriction requirement in the parent application will not be excused even if the examiner suggested the claim and failed to appreciate that it was improper in the divisional application.[79] In determining whether there is consonance, "the actual restriction groupings [of the examiner], not the written descriptions thereof, control for purposes of ascertaining if subsequent amendments to original claims are consonant with the substantive restrictions drawn by the examiner."[80]

Other circumstances where the safe haven of Section 121 is unavailable include where "the divisional application was voluntarily filed by the applicant and not in response to a PTO restriction requirement" and where "the restriction requirement was withdrawn by the examiner."[81] Reaffirming the dictate that the protections of Section 121 are lost when a voluntary divisional is filed, the Federal Circuit recently held that "the earlier application must contain formally entered claims that are restricted and removed, and...claims to the second invention [must] reappear in a separate divisional application after the restriction."[82] It is insufficient merely if the original application provides support for claims that were first entered formally in a divisional application.[83]

An instructive and recent application of the consonance requirement to deny the protections of Section 121 is *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343 (Fed. Cir. 2004). In that case, the applicants were not permitted to rely on Section 121 even though they had complied with a restriction requirement entered in their divisional application. The problem was that the restriction requirement in the

77 *Applied Materials*, 98 F.3d at 1568.

78 *Id.*

79 *Gerber*, 916 F.2d at 688 (noting that presentation of improper claim in divisional application cannot be excused on the ground that "the examiner made me do it").

80 *Texas Instr. Inc. v. United States Int'l Trade Comm'n*, .988 F.2d 1165, 1179 (Fed. Cir. 1993).

81 *Studiengesellschaft*, 784 F.2d at 360 (Newman, J., concurring).

82 *Geneva Pharm.*, 349 F.3d at 1379.

83 *Id.*

divisional — and thus the issued claims — was not consonant with the restriction requirement in the parent application.[84]

Bristol-Myers filed a patent application in 1972 (the '989 application), receiving two different restriction requirements (in 1973 and 1974).[85] Bristol-Myers then filed a continuation application in 1977 (the '955 application), which included all the claims filed with the 1972 application.[86] A new restriction requirement was issued in the '955 application in 1977.[87] Ultimately, a patent issued from the '989 application with claims directed to one of the groups specified in the 1977 restriction requirement in that application.[88] Before that patent issued, Bristol-Myers filed another continuation application (the '706 application) claiming non-elected subject matter from the '989 and '955 applications.[89] The Patent Office issued a different restriction requirement in the '706 application.[90] In 1983, Bristol-Myers filed yet another continuation application, which elicited yet another restriction requirement.[91] In 1987, that application issued as the patent-in-suit (the '927 patent).[92]

The court held that Bristol-Myers could not receive the protection of § 121 with respect to the earlier patent issuing from the '955 application filed in 1977 because that application "began a new proceeding in which all of the original claims of the [1972] '989 application were once again presented for examination."[93] The 1977 restriction requirement was "different from and inconsistent with" the restriction requirements in the earlier applications.[94] "By imposition of a new and different restriction requirement and failing to make any reference to the restriction requirements imposed in connection with the parent application, the examiner made clear that the previous restriction requirements did not carry over to the '955 application."[95]

The court further found that the record did not support the inference that any of the pre-1977 restriction requirements were carried

84 *Bristol-Myers Squibb Co. v. Pharmachemie B.V.*, 361 F.3d 1343, 1347-50 (Fed. Cir. 2004).
85 *Id.* at 1345.
86 *Id.* at 1345-46.
87 *Id.*
88 *Id.* at 1346.
89 *Id.*
90 *Id.*
91 *Id.*
92 *Id.* at 1347.
93 *Id.* at 1348.
94 *Id.* at 1349.
95 *Id.*

forward to later applications.[96] This conclusion was supported by the fact that the record did not indicate that the Bristol-Myers applicants had proceeded under the assumption that the 1973 restriction requirement was still in effect.[97]

Notably, after its lengthy analysis and conclusions that the earlier restriction requirements did not carry forward, the Federal Circuit declined to affirm or reverse the district court, but instead vacated and remanded "[i]n light of the complexity of the factual record."[98] In so doing, the court observed that

> [w]hether further analysis of the sequence of applications, restriction requirements, and responses by the applicants *may reveal other grounds* for concluding that the protection of section 121 should be extended to some or all of the claims of the [1977 application] is a matter for the district court to address in the first instance.[99]

The court offered no guidance as to what "other grounds" might suffice or how the district court might come to a different conclusion that the Federal Circuit.[100]

Certain practice considerations emerge from the Federal Circuit cases dealing with the interplay of Section 121 and obviousness-type double patenting. Applicants should present claims in the parent application drawn to all aspects of the invention as to which divisional applications may later be desired, so that a formal restriction requirement is entered as to them. Applicants should ask the examiner to clarify any ambiguity in a restriction requirement. When filing a divisional application, applicants should present claims only drawn to the subject matter of a single, non-elected group specified in the parent's restriction requirement. Finally, applicants should not add claims or claim limitations that destroy consonance, even if suggested by the examiner.

V. Double Patenting and the Duty of Disclosure

Patent applicants (and others substantively involved in prosecution of the application) have a duty to disclose to the examiner all information known to them to be "material to patentability."[101] A failure

96 *Id.*
97 *Id.*
98 *Id.* at 1350.
99 *Id.* (emphasis added).
100 *See id.* at 1354-55 (Newman, J., dissenting).
101 37 C.F.R. § 1.56.

to disclose such "material" information, coupled with an intent to mislead, can result in a finding of inequitable conduct, rendering the patent unenforceable.[102]

Patent office policy requires imposition of provisional double patenting rejections for commonly-owned co-pending applications with patentably indistinct claims.[103] Thus, the Federal Circuit has held that the existence of a commonly-owned co-pending patent application is "highly material" to patentability if it "could have conceivably served as the basis of a double patenting rejection."[104]

Further, a co-pending application was found to be material even where there was a terminal disclaimer in the application-at-issue to a date prior to the expiration date of any patent issuing on the co-pending application, because there was no obligation of common ownership.[105],[106] That is, by not citing the co-pending application, applicants avoided the necessity of a terminal disclaimer specifically as to the co-pending application — and avoided the necessity of insuring that those applications remain commonly owned. That common ownership provision was deemed material.[107]

Failure to disclose material co-pending, commonly owned applications can result in a finding of inequitable conduct and concomitant unenforceability, *if* the requisite intent to mislead also is found to exist.[108] Interestingly, in the two cases in which the Federal Circuit addresses the duty to disclose co-pending application, the court found the evidence of intent to mislead insufficient to support an inequitable conduct finding.[109] Nevertheless, prudence would dictate making such applications of record.

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102 *E.g., Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001).

103 M.P.E.P. § 804.

104 *Akron Polymer Container Corp. v. Exxel Container Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998); M.P.E.P. §§ 2001.06(b), 2004(¶9).

105 *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-67 (Fed. Cir. 2003).

106 An independent basis for finding a co-pending application material is that it contains a substantially similar claim that was rejected by another examiner. Such an "adverse decision by another examiner" meets the materiality standard under Rule 56. *Id.* at 1368.

107 *Id.*

108 *Id.* at 1366-68; *Akron Polymer*, 148 F.3d at 1382-84.

109 *Dayco*, 329 F.3d at 1366; *Akron Polymer*, 148 F.3d at 1384.

VI. Conclusion

The possibility of patent term extensions and the requirement of common ownership make double patenting issues an important consideration even for applications filed after June 8, 1995, for which patent term runs from filing date rather than issue date. Double patenting considerations are particularly important for biotechnology and pharmaceutical patents, because patent term extensions often are sought for those patents, and (3) it can take so long to bring a biotechnology or pharmaceutical product to market that the commercially useful life of the patent may come at the very end of the term, making every lost year (or month) extremely significant.